# Operating Instructions
# WD 290

Item Number: 10532-0150-EN
Version: 001-07/09

Belimed
Infection Control

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# 1 Introduction

## 1.1 Before you read on

Your product meets high standards and is easy to operate. Nevertheless, please take time to read these instructions carefully. You will become familiarised with your product and be able to use it to its best.

## 1.2 Target group

These instructions are a component of the product and are intended for the following personnel:

| | |
|---|---|
| ***Installation instructions*** | Installer; Operating company; Technical support |
| ***Operating instructions*** | Operator; Operating company; Technical support |
| ***Technical manual*** | Operating company; Technical support |

They must be accessible for this group of persons!

## 1.3 Changes

The text, graphics and data correspond to the technical status of the product at the time of going to print. Changes due to further development may occur.

Language original for this document is German (DE)

## 1.4 Symbols and notices used

The following symbols and occupational safety alerts used throughout the documentation are important to avoid harm to health and life.

**Danger**
Indicates a hazard with high risk which, if not avoided, causes death or serious injury.

**Warning**
Indicates a hazard with medium risk which, if not avoided, can cause death or serious injury.

**Caution**
Indicates a hazard with low risk which, if not avoided, can cause minor or moderate injury.

**Note**
Operating tips and useful information on the best possible utilization.


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# 2 For your safety

We affirm with the EC Declaration of Conformity and the CE mark that this product complies with the basic health and safety requirements in accordance with Directive 93/42/EEC Annex II (see Chap. 18 "Conformity and certifications").

Hazards may still arise from the product if it is used incorrectly by inadequately trained personnel or not as intended.

## 2.1 Intended use

This product is exclusively approved for the uses stated in the instructions. Namely for central sterilisation, substerilisation in surgery, in hospitals and in laboratories. All other applications are considered as non-intended use.

## 2.2 Care responsibilities for dealing with the device

- Only use **original racks, spare parts and accessories**
- **Load racks as intended** (see Chap. 8 "Loading and identifying racks")
- **Daily maintenance work** on the device must be performed regularly and according to instructions (see Chap. 14 "Daily maintenance and cleaning tasks")
- **Validation** of the program parameters must be performed regularly (see Chap. 2.6 "Process validation")
- **Installation, deinstallation, maintenance or modification** must only be performed by persons authorised by Belimed

## 2.3 Instruction of personnel

This product must only be used, maintained and repaired by authorised, trained and briefed personnel. This assumes that these instructions are read and understood.

Responsibilities and competencies in operation, servicing and maintenance must be clearly defined and observed.

## 2.4 Safety instructions on the device

| | |
|---|---|
| | Warning ***"Dangerous voltage"*** |
| | Warning ***"Hot surface"*** |
| | Warning ***"Caustic substances"***<br>Follow safety instructions of the dosage media manufacturer! |

## 2.5 Fields of application for the device

Cleaning and reconditioning of:

- Surgical instruments
- Minimally invasive instruments
- Instruments for anaesthesia and intensive care
- Baby bottles and teats
- Containers
- OT Shoes
- Laboratory instruments used in research and production
- Rigid endoscopes
- Eye instruments
- Neurosurgery

**Warning**
No single-use products may be reconditioned! Always adhere to the instructions of the medical device manufacturer!

## 2.6 Process validation

The aim of process validation is to achieve a high level of safety in the reconditioning of medical devices in order to afford the operators and patients the greatest possible protection.

Process validation consists of:

a) **Type testing** / **factory testing**

b) **Process validation consisting of:**
   - IQ (Installation Qualification)
   - OQ (Operational Qualification)
   - PQ (Performance Qualification)

c) **Routine testing** / **Annual requalification**

**Note**
Further information on process validation may be obtained from Belimed Customer Service.

**Caution**
Validation must only be carried out by authorised persons!

Devices must only be operated with processes validated in accordance with regulations! Only use components *(items to be washed, racks, programs and dosage media)* which have been validated together.

The safety of operators and patients may be compromised if the devices used are not validated in accordance with the regulations.


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# 3 Device description

## 3.1 Device loading side (LS)

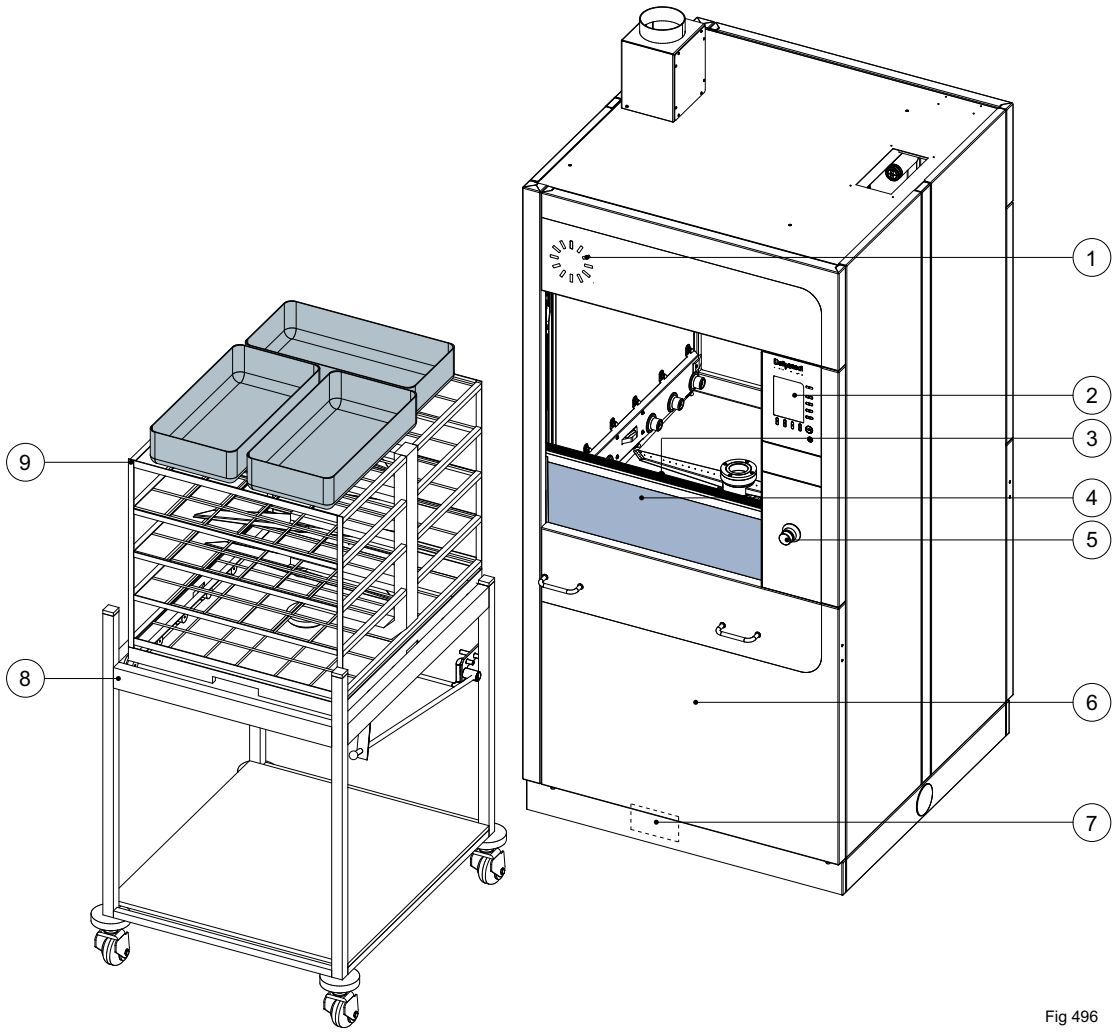


Fig 496

1 Process status display
2 Operating unit
3 Safety switch actuator
4 Washing chamber door
5 Emergency Stop
6 Lower front panel
7 Location of power rating plate
8 Transfer cart
9 Rack

## 3.2 Device unloading side (US)

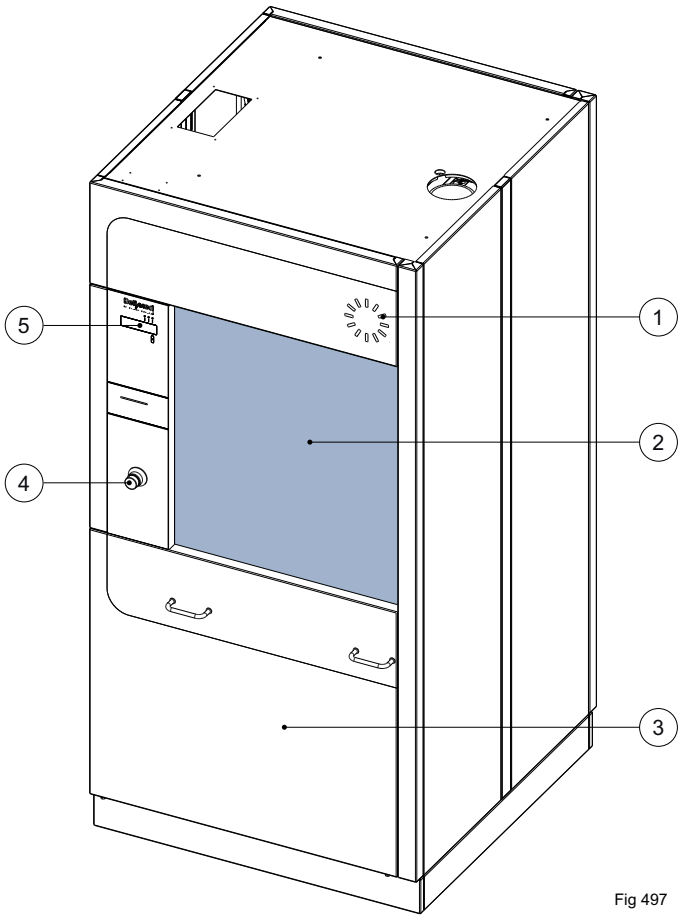


Fig 497

1 Process status display
2 Washing chamber door
3 Lower front panel
4 Emergency Stop
5 Operating unit


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## 3.3 Operating unit on loading side (LS)

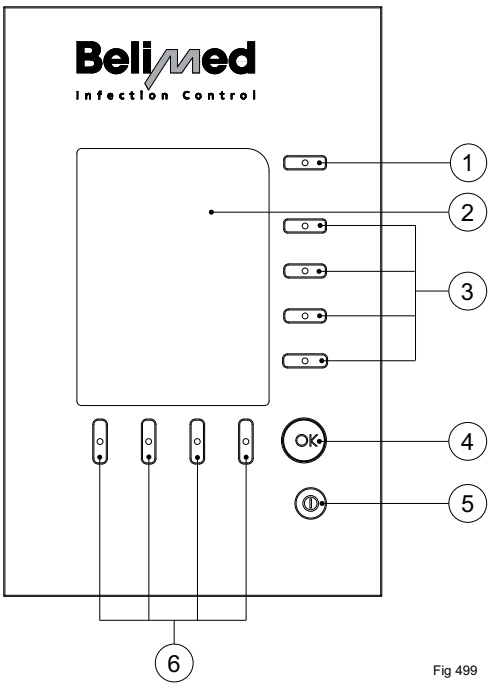


Fig 499

1) **Menu button**
2) **Display**
   – Displays the
   status bar, communication bar, activity bar, selection options
3) **Selection buttons**
4) **Confirmation button <OK>**
5) **On/Off button**
6) **Activity buttons**

### 3.3.1 Description of operating unit on loading side

**Status bar**

The status bar draws attention to certain settings and events by means of icons and data. The status bar is device-dependent and in each case has the same content on all screens.

***Status bar icons***

| Symbol | Description | Symbol | Description |
|---|---|---|---|
| | Message inactive | | Warning active |
| | Error active | | Doors locked |
| | Doors open | | Doors closed |
| | Door on loading side open | | Door on unloading side open |
| | Automatic system active | | Automatic system inactive |
| | Automatic system error | | |

### Communication bar

The communication bar comprises an icon for the scroll wheel and a two-line text display. The scroll wheel icon indicates, whether the operating unit is displaying the *"Home screen"* or the *"Information screen"* .

#### *Communication bar icons*

| Symbol | Description | Symbol | Description |
|---|---|---|---|
| | Scroll wheel Home | | Scroll wheel Info |

### Activity bar

The respective function options of the activity buttons are shown in the activity bar. For screens with several pages, the respective page number and total number of pages is additionally displayed in the activity bar.

#### *Activity bar icons*

| Symbol | Description | Symbol | Description |
|---|---|---|---|
| | Cursor forward | | Cursor back |
| | Delete | | Delete all |
| | Cursor up | | Cursor down |
| | Capital letters | | Lower case letters |
| | Numbers | | New |
| | Page forward | | Page back |
| | Open door | | Close door |
| | Value minus (smaller) | | Value plus (larger) |
| | Back | | |
| | No user logged on | | New user |
| | Program pause | | Program start |
| | Deactivate door contact pressure | | Activate door contact pressure |


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## 3.4 Operating unit on unloading side (US)

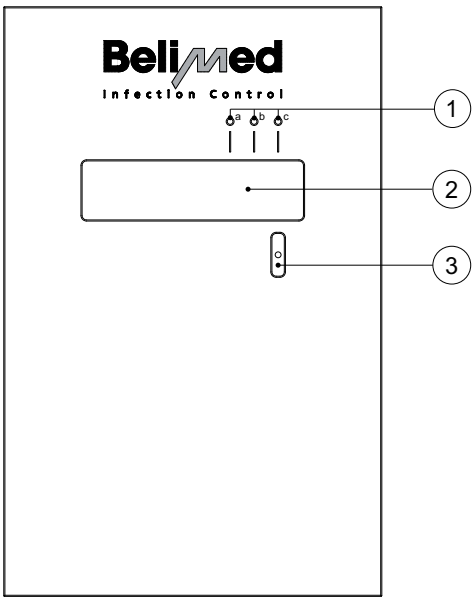


Fig 500

1) **LED Displays**
   - a) LED Red flashes - Warning active; LED Red lights permanently - error active
   - b) LED Green lights permanently - Program cycle active
   - c)LED Green lights permanently - Doors locked
2) **Display**
   - Displays the Status bar, activity bar
3) **Activity button**

### 3.4.1 Description of operating unit on unloading side

**Status bar**

The status bar draws attention to certain settings and events by means of icons and data.

***Status bar icons***

| Symbol | Description | Symbol | Description |
|---|---|---|---|
| | Automatic system active | | Automatic system inactive |
| | Doors locked | | |
| | Doors open | | Doors closed |
| | Door on loading side open | | Door on unloading side open |

**Activity bar**

The respective function option of the activity button is shown in the activity bar. The options available depend on the respective machine status of the device.

***Activity bar icons***

| Symbol | Description | When displayed |
|---|---|---|
| | Open door | Program completed correctly, door ready to open |
| | Close door | Door ready to close |
| | Brightness and background illumination setting | User setting, display settings for unloading side |
| | Contrast setting | User setting, display settings for unloading side |
| | Confirmation of display settings | User setting, display settings for unloading side |

## 3.5 Process status display

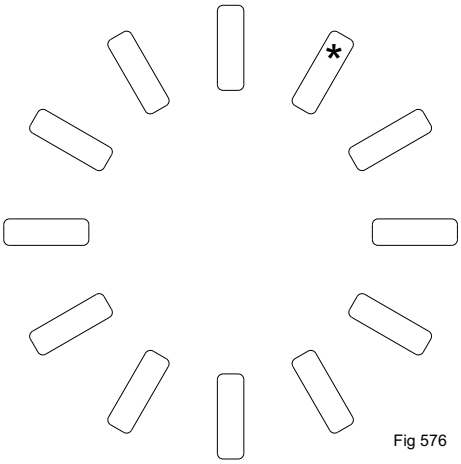


Fig 576

- **Display starting position**
  - All LEDs = Dark (no display)
- **Program in Progress-Display**
  - see description
- **Error display**
  - All LEDs = Red, flashing
- **Process interruption display**
  - All LEDs = Red, flashing

* = 1. LED

### 3.5.1 Process status display description

**Process status display**

The process status display is located above the washing chamber door on the loading side and the unloading side. The process status display shows the current operating status of the device.


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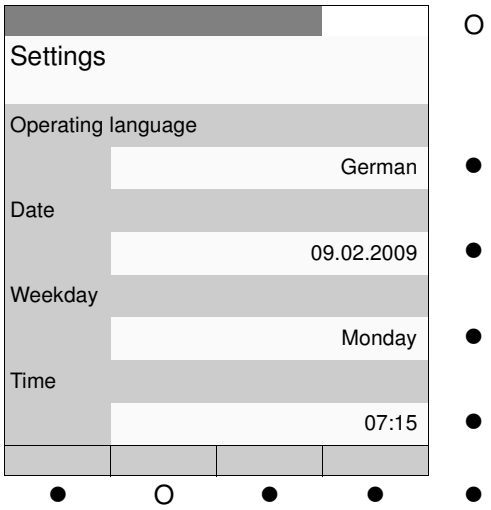
Display while program is in progress:

- If the remaining run time is more than 55 min, a running light which rotates clockwise is displayed.
- If the remaining run time is between 50 and 55 min, the first LED lights up. Every 5 min, a further LED lights up.
- At the end of the program, all 12 LEDs flash.
- The LEDs are turned off when the door is opened or in the event of an error.

## 3.6 Procedure for changing settings

Example - Setting the date:




▶ Select date display

The current cursor position is lighted up

▶ Select value to be modified using the activity button

▶ Increase value using activity button , or decrease with

▶ After setting all values, confirm settings with <OK> -Button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## 3.7 Alphanumeric entry

The alphanumeric entry screen consists of three separate screens.

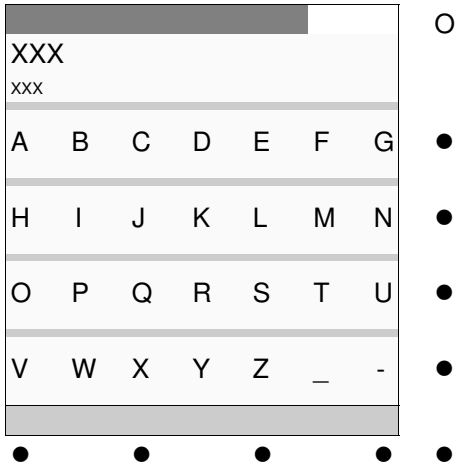
1st screen = Capital letters

2nd screen = Lower case letters

3rd screen = Numbers

To change screens, press activity button ABC > abc > 123 .

Example - Capital letters:




### 3.7.1 Procedure for alphanumeric entry

If a text is to be edited, or if entry of a user password is required, the screen switches to alphanumeric entry, and the text to be edited is copied into the line. The cursor is positioned after the last character.

The initial screen is always the entry screen with capital letters. The line is defined according to the screen that was selected before.

Only one character is edited at a time. The cursor position is indicated by the background of the character flashing, the background alternating between white and light green.

By pressing the <OK> -Button, the edited text is saved and the display reverts to the original screen.

### 3.7.2 Operating buttons

***Selection buttons***

The characters of the respective line can be selected using the selection buttons. Pressing for the first time selects the first character of the line. Pressing again causes the cursor to jump to the next character on the right. After the last character, the cursor returns to the first character again.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### *Confirmation button*

| | |
|---|---|
| Icon: | OK |
| Icon description: | Confirmation button |
| Function when activated: | Display reverts to original screen; the edited text is saved |

### *Activity buttons*

| | |
|---|---|
| Icon: | |
| Icon description: | Back |
| Function when activated: | Display reverts to original screen; the edited text is not saved |

| | | | |
|---|---|---|---|
| Icon: | > ABC > | > abc > | > 123 > |
| Icon description: | Capital letters | Lower case letters | Numbers |
| Function when activated: | Screen switches to capital letters | Screen switches to lower case letters | Screen switches to numbers |

| | |
|---|---|
| Icon: | |
| Icon description: | Delete |
| Function when activated: | Deletes character at cursor position; cursor stays at this position |
| Special function: | For password entry (depending on activated option), it is possible to log on the user under *"No Identification"*; Display <NIdent>; when a character is entered, the function switches to *"Delete"* -activity |

| | |
|---|---|
| Icon: | |
| Icon description: | Cursor forward |
| Function when activated: | Cursor moves forward one position |

# 4 Pre-treatment of the medical devices

## 4.1 Responsibility for pre-treatment

**Caution**
Always observe the manufacturer's specifications for the medical device to be treated!

The operating company is responsible for pre-treatment of medical devices. The best possible washing results are only to be achieved with correct pre-treatment according to instructions.

### 4.1.1 SOP (Standard Operating Procedures)

The contents of the following criteria and specifications must be defined:

- Product responsibility
- Transport routes and disposal time (time for soiling to dry in)
- Type of soiling (blood, ointments, bone meal...)
- Material properties and compatibility of the items to be washed (risk groups acc. to RKI Ordinance)
- Consideration of all operating instructions and reconditioning regulations for medical devices
- Necessary knowledge of the medical devices to be reconditioned
- Maintenance plan and regular inspections

Belimed recommends producing work instructions which describe the procedure within a working process.

## 4.2 Preparation of the medical devices

**Caution**
Not all medical devices are suitable for mechanical reconditioning (see Chap. 2.5 "Fields of application for the device")

All inner and outer surfaces must be accessible for cleaning (open valves, taps, articulated instruments...). Special attention should be given to the lumina. Disassemble MIS or other complex instruments according to the manufacturer's specifications.


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## 4.3 Pre-cleaning pre-treatment

Remove coarse soiling immediately after use. Dried-on blood or tissue reduces the effectiveness of cleaning.

### 4.3.1 Impairment of subsequent cleaning

Various treatments fix proteins and may contribute to preserving prion infectiosity.

The following pre-treatment methods may cause impairments in subsequent washing:

- Pouring antiseptic solutions on the items to be rinsed
- Pre-treatment with aldehydic disinfectants
- Pre-treatment with alcohol solutions
- Aldehyde and alcohol vapours

**Note**
We recommend cold rinsing of the pre-treated washing utensils prior to mechanical cleaning and disinfection.

**Caution**
Excessive foam can prevent pressure building up in the cleaning system and therefore impair optimal contact between the cleaning agent and the items to be washed.

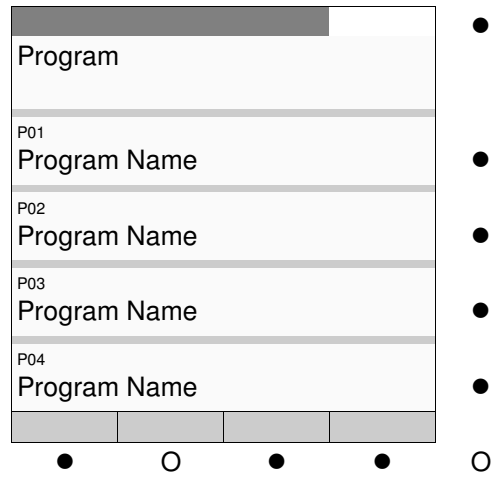
# 5 Preparation of the device

**Warning**
Only operate the device if it is in a technically faultless condition! Damaged or defective components must immediately be reported to technical support.

After a prolonged period without using the device (approx. 1 week), the device must be prepared in accordance with the specifications for daily maintenance work (see Chap. 14 "Daily maintenance and cleaning tasks").

- ▶ Open utility supply
- ▶ Check the quantity of dosage media (see Chap. 16 "Errors")
- ▶ Switch the device on with button ⏻ (see Chap 3.3 "Operating unit on loading side (LS)"). The start screen appears on the operating unit

**Table 1: Start screen**




- ▶ Press the menu button (see Fig. 686). The menu screen is displayed

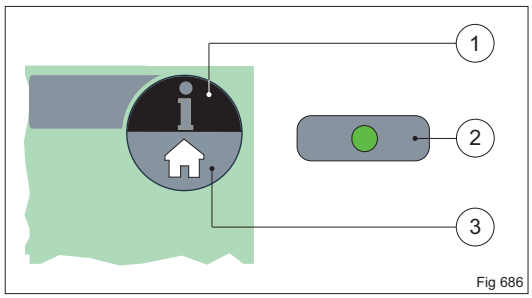


Fig 686

1 Menu
2 Menu button
3 Operating mode


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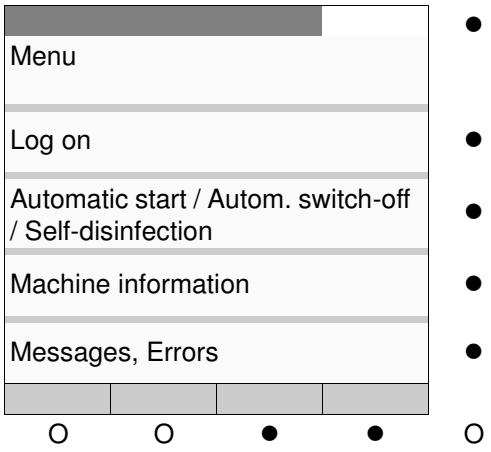
**Table 2: Menu screen**




**Menu displays:**

- **Log on**
  (see Chap. 6 "User log-on")
- **Automatic start** / **Autom. switch-off** / **Self-disinfection**
  (see Chap. 7 "Automatic start and switch-off, Self-disinfection")
- **Machine information**
  e.g. machine type, machine name, machine number, ...
- **Messages, Errors**
  Messages: Rectify error (see Chap. 16 "Errors")
  Alerts: Notify technical support
- **Settings**
  e.g. operating language, date, time, ...
- **Cleaning the screen**
- **User Management**
- **Measurements**

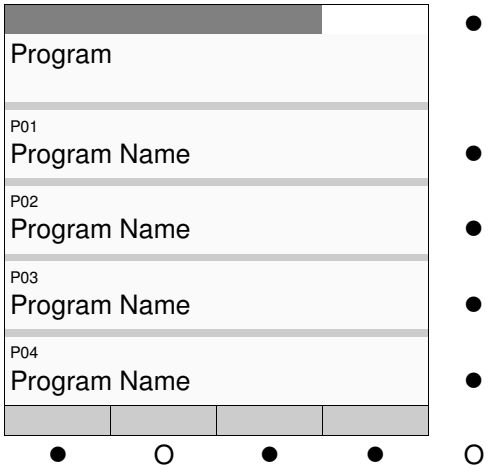
# 6 User log-on

The user must log on each time before using the device. The log-on data are forwarded to the printer or the digital documentation system and assigned to the respective batch.

Log-on data are entered via the operating unit or via barcode reader.

## 6.1 Log-on via operating unit

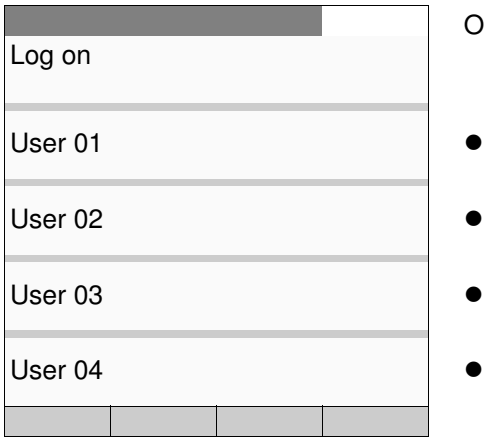
After switching on the device, a program can be selected.




● O ● ● O

▶ Select program. The background of the selected program is displayed in a light shade

▶ Confirm selection by pressing <OK> -Button. User log-on appears




● O ● ● O

▶ Select list. The display for user password entry appears

▶ Enter user password via operating unit

Display:

O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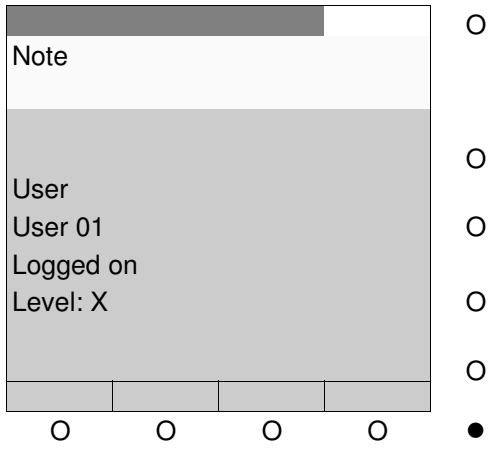
**Note**
The length of the password input is limited to 20 characters. The activity button can only be pressed if no character has been entered yet.

For entry by the operating unit we recommend a list of numbers with the corresponding names (see Example 1).

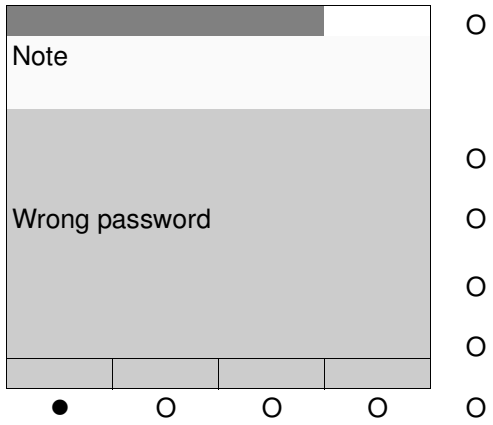
Example 1:

| No. | Name |
|---|---|
| 1 | M. Smith |
| 2 | H. Jones |
| 3 | A. Baker |
| etc. | ... |

▶ Confirm entry by pressing <OK> -Button. The notification display for the log-on appears




***or***

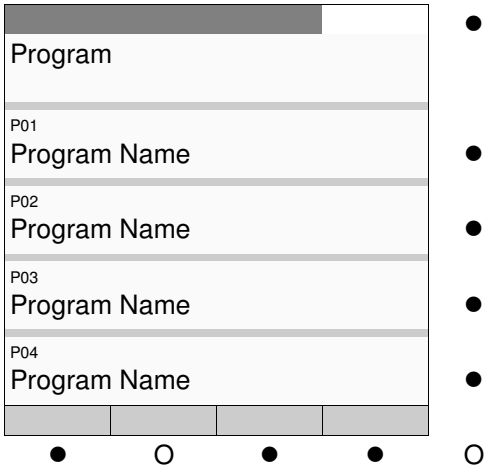



**Note**
The user can be logged on directly via password. The system finds the user by matching the password.

▶ Device is ready for starting the program

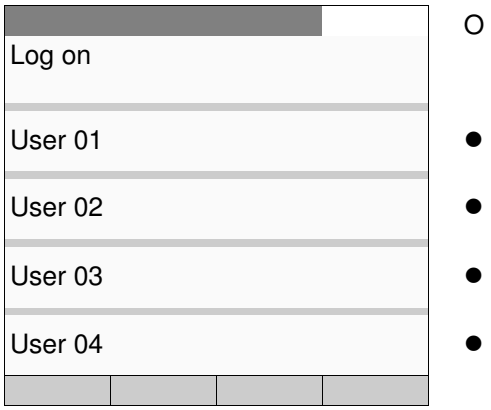
## 6.2 Log-on via barcode reader

After switching on the device, a program can be selected




▶ Select program. The background of the selected program is displayed in a light shade

▶ Confirm selection by pressing <OK> -Button. User log-on appears




▶ Read in the barcode via the barcode reader

**Note**
The length of the identification input is limited to 20 characters.

Barcodes for name labels can be produced from the Internet by the user himself (free of charge). (*http://www.barcodemagic.com/barcodemagic.html*).

▶ Confirm entry by pressing <OK> -Button. The notification display for the log-on appears (see Chap. 6.1 "Log-on via operating unit")

Sample barcode:

Fig 571

**First name** / **last name**
Patrick Schwarz

▶ Device is ready for starting the program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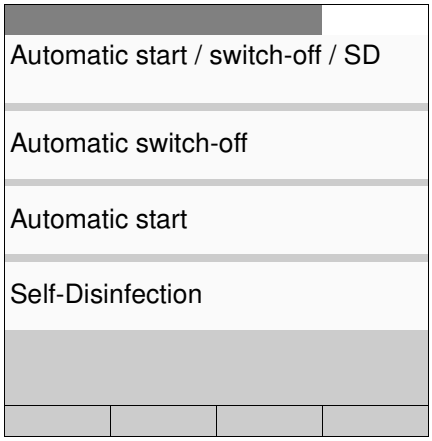
# 7 Automatic start and switch-off, Self-disinfection



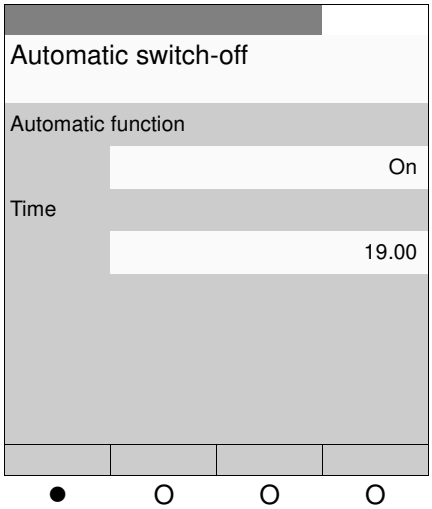

The display is selected via the menu screen (see Table 2 in Chap. 5 "Preparation of the device").

## 7.1 Automatic switch-off

In an automatic start, a washing program can be started automatically at a time which can be freely selected. After completing the program, the device switches automatically to *"Stand by"* -Mode. In this mode, the device does not continue to keep the DI tank at the specified temperature.

### 7.1.1 Activating and setting the automatic switch-off function

▶ Select *"Automatic switch-off"* -Function




***Automatic function:***

Selection *On / Off*

***Time:***

Time for automatic switch-off can be freely selected.

▶ Select function and enter value for setting via operating unit

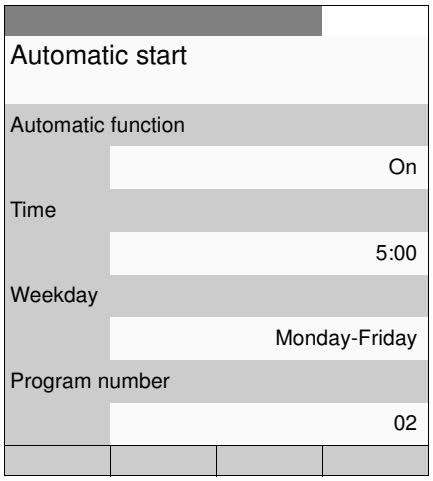
▶ After entering settings, confirm values by pressing <OK> -Button

## 7.2 Automatic start

In an automatic start, a washing program can be started automatically at a time which can be freely selected.

### 7.2.1 Activating and setting the automatic start function

▶ Select *"Automatic start"* -Function




● O O O ●

O ***Automatic function:***
Selection *On / Off*
***Time:***
● Time for automatic start can be freely selected.
***Weekday:***
● Weekday selection. Options see note below
***Program number:***
● Selection of an existing program
●

▶ Select function and enter value for setting via operating unit

▶ After entering settings, confirm values by pressing <OK> -Button

**Note**
Selection of weekly programs: Monday-Friday; Monday-Saturday; Monday-Sunday; Sunday-Friday; Saturday-Thursday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## 7.3 Self-Disinfection

**Caution**
**Never carry out self-disinfection without a rack!**
**Always carry out self-disinfection with empty rack!**

### 7.3.1 Why self-disinfection?

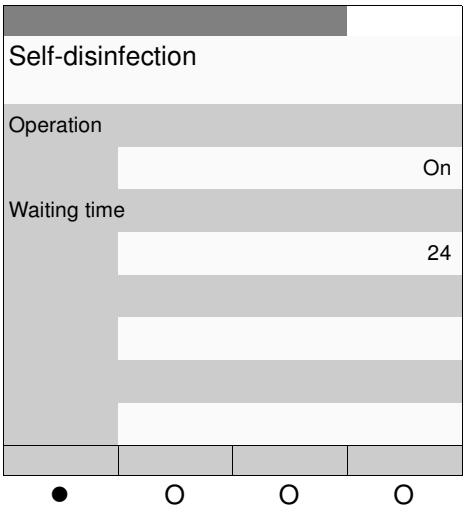
Microorganisms form in the washing chamber, tubing and PW tank after a prolonged period not using the device. Following a thermal disinfection step, residues of dead germs on the medical device may constitute a risk for patients.

If self-disinfection is ***active***, the user is requested to perform self-disinfection after a programmed period (24 hours as standard) following the last program run.

**Note**
When the power supply is interrupted (main switch *"Off"*), the timer is inactive. For this reason, the request *"Start self-disinfection"* always appears when the device is switched on and self-disinfection is active.
**Always carry out self-disinfection with empty rack!**

### 7.3.2 Activating and setting the self-disinfection function

▶ Select *"Self-disinfection"* -Function.




○ ***Operation:***
Selection *On / Off*
***Waiting time:***
● Waiting time can be freely selected. *1-99 h*.
●
○
○
● ○ ○ ○ ●

▶ Selection of function and enter value for setting via operating unit

▶ After entering settings, confirm values by pressing <OK> -Button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### 7.3.3 Starting self-disinfection

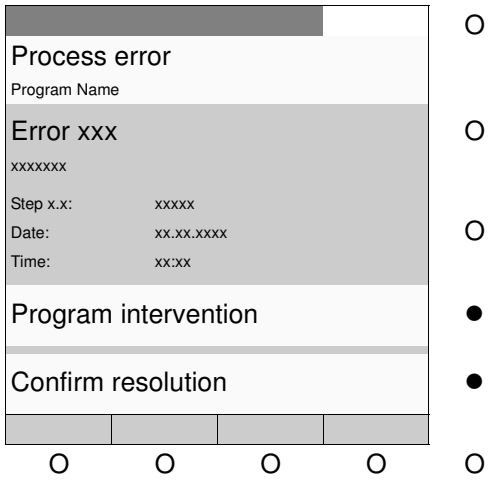
- ▶ Open washing chamber door with activity button
- ▶ Insert empty rack

**Caution**
Do not wash any items with the self-disinfection program! No cold pre-rinse is carried out. There is a risk of excessive foam formation and fixing proteins.

- ▶ Close washing chamber door with activity button .
  - ▶ User identification (see Chap. 6 "User log-on")
- ▶ Start self-disinfection in the *"Self-disinfection"* sub-menu
  *This is always the last of the programs available*

**Procedure in case of error:**

- ▶ If an error occurs during operation, resolve the error and confirm error resolution.
  - ▶ Select *"Confirm error resolution"* -Function




- ▶ If the error persists -->see Chap. 16 "Errors"!
- ▶ If the error cannot be rectified, technical support must be informed

**Danger**
If smoke is emitted or water escapes, immediately **press Emergency Stop** and disconnect the device from the building power supply. Call technical support to have system repaired.

- ▶ End of program is displayed and additionally indicated by flashing process status display

**Note**
For manual loading and unloading, unload the rack in reverse from the LS after the program has ended. The US washing chamber door remains locked.

For automatic loading and unloading, the self-disinfection function is inactive.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# 8 Loading and identifying racks

## 8.1 Loading racks

The loading of racks has a significant influence on the washing outcome. **For correct and intended loading it is absolutely necessary to follow the instructions supplied with the rack.**

**Danger**
Always wear protective goggles and gloves when handling the items to be washed. **Soiled items to be washed may cause infections!**

## 8.2 Rack identification

The rack identification is forwarded to the printer or the digital documentation system and assigned to the relevant batch.

Identification is entered via the operating unit or via barcode reader.

### 8.2.1 Rack identification via operating unit

Display:

O

▶ Enter the identification number via the operating unit.

**Note**
The length of the identification input is limited to 20 characters. The activity button can only be pressed if no character has been entered yet.

▶ Confirm entry by pressing <OK> -Button

### 8.2.2 Rack identification via barcode

Display:

O

▶ Read in the barcode via the barcode reader

**Note**
The length of the identification input is limited to 20 characters (see Chap. 6.2 "Log-on via barcode reader").

Barcodes can be produced from the Internet by the user himself (free of charge). (*http://www.barcodemagic.com/barcodemagic.html*).

▶ Confirm entry by pressing <OK> -Button

# 9 Batch content identification

The identification of batch content is forwarded to the printer or the digital documentation system and assigned to the relevant batch.

Detection takes place via the operating panel or by means of barcode reader.

## 9.1 Batch identification via barcode

Display:

O

▶ Read in the barcode via the barcode reader

**Note**

The length of the identification input is limited to 20 characters (see Chap. 6.2 "Log-on via barcode reader").

Barcodes can be produced from the Internet by the user himself (free of charge). (*http://www.barcodemagic.com/barcodemagic.html*).

Reading-in is terminated automatically after reaching a max. of 18 batch contents.

▶ Confirm entry by pressing <OK> -Button

Example:

Fig 227


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# 10 Loading

**Danger**
Always wear protective goggles and gloves when loading. **Soiled items to be washed may cause infections!**

## 10.1 Manual loading

▶ Latch transfer cart with loaded rack onto the device (Fig. 578 Pos.1)

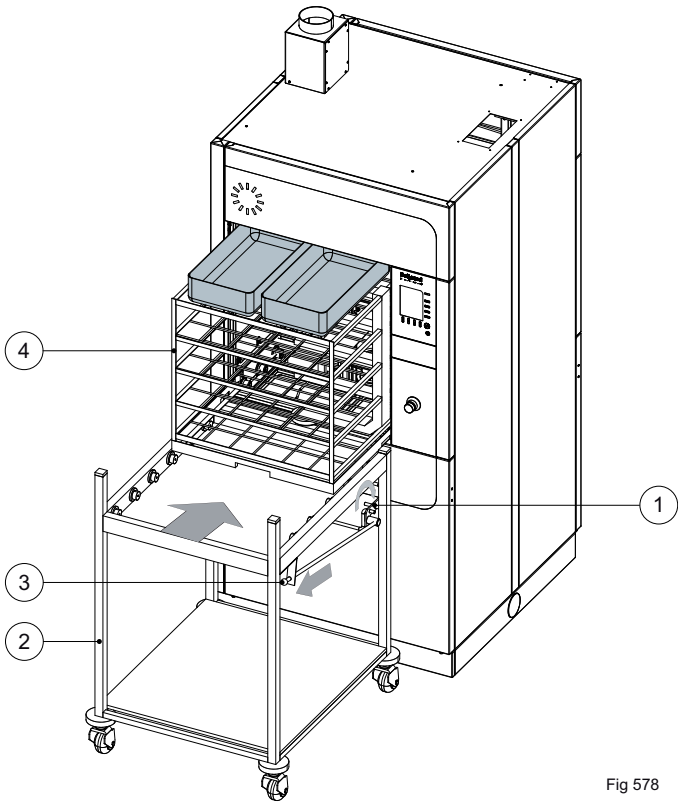


Fig 578

1 Attachment and detachment hook
2 Transfer cart
3 Unlocking lever
4 Rack

▶ Open washing chamber door with activity button .

▶ Insert the loaded rack into the washing chamber (Fig. 578)

- Rack docking site must coincide with device docking site
- Rack must snap into place on the retainer (Fig. 579)

**Caution**
Sharp or pointed objects may fall down when inserting the rack. This can cause injuries.

**Wash arms must not be blocked by objects that are too high, or that protrude below the rack. Check rotation by hand!**

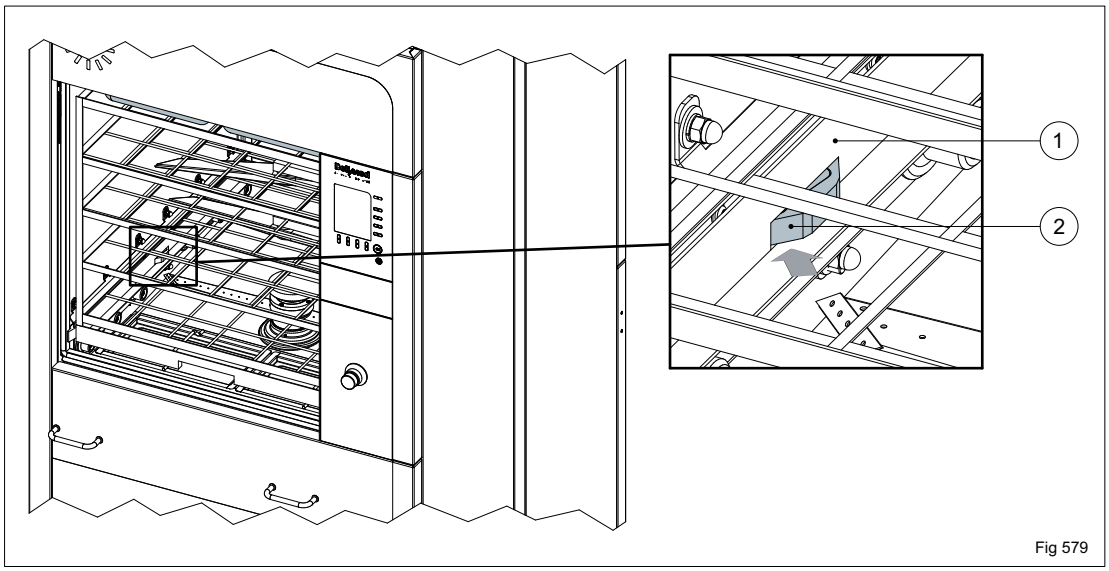


Fig 579

1 Rack
2 Retainer

▶ Close washing chamber door with activity button

▶ Device is ready to start

Display:

| | | | | |
|---|---|---|---|---|
| Program | | | | ● |
| P01 Program Name | | | | ● |
| P02 Program Name | | | | ● |
| P03 Program Name | | | | ● |
| P04 Program Name | | | | ● |
| | | | | |
| ● | O | ● | ● | O |

**Note**
Check to ensure that date and time are correct. These data are important for batch documentation. Report inconsistencies to technical support immediately!


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## 10.2 Automatic loading and unloading (optional)

For correct operation and maintenance in accordance with specifications, it is absolutely necessary to follow the operating instructions for the automatic loading and unloading module included in delivery.

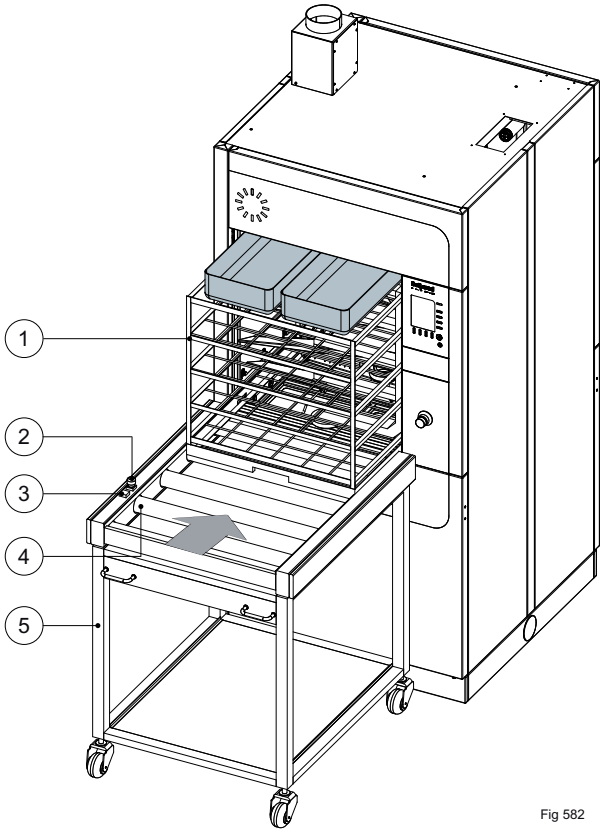



Fig 582

1 Rack
2 Emergency Stop
3 Operating buttons
4 Rollers with automatic drive
5 Automatic loading and unloading module

# 11 Washing and disinfection

## 11.1 General instructions

**Warning**
Only operate the device with the original device panelling! Uncontrolled escape of water due to breakage of pipes or ruptured tubes can cause scalding. Only remove the device panelling once the device is disconnected from the mains supply.

**Emergency Stop Function**

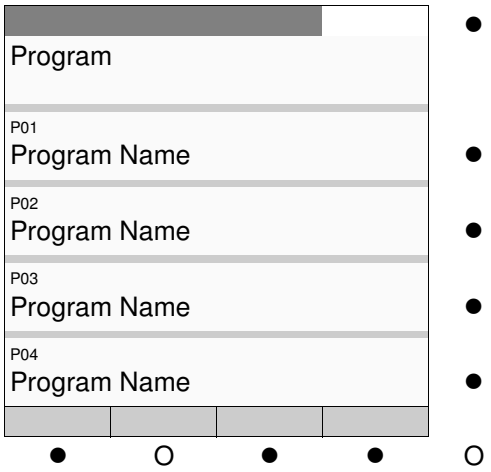
Emergency Stops are located on the loading and on the unloading side. Activating the Emergency Stop immediately stops and terminates a running process.

If a problem occurs during a process, the following steps must be taken:

- ▶ Press Emergency Stop

  The current process is stopped and terminated
- ▶ Rectify error (see Chap. 16 "Errors")
- ▶ Restart program

## 11.2 Washing, disinfecting and drying




- ▶ Select required program
- ▶ Confirm program selection by pressing <OK> -Button

  Program cycle starts

*These steps proceed automatically for automated program recognition (optional).*

**Note**
For *"Automatic program recognition"*, the items to be washed must be checked whether they fit the program name!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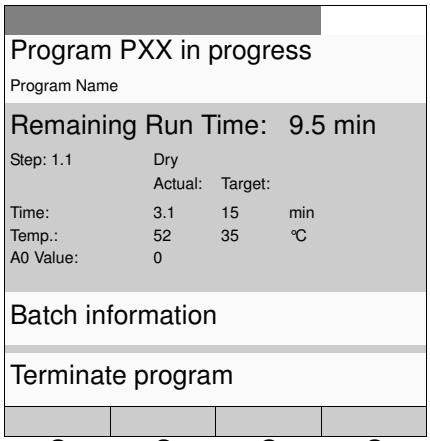
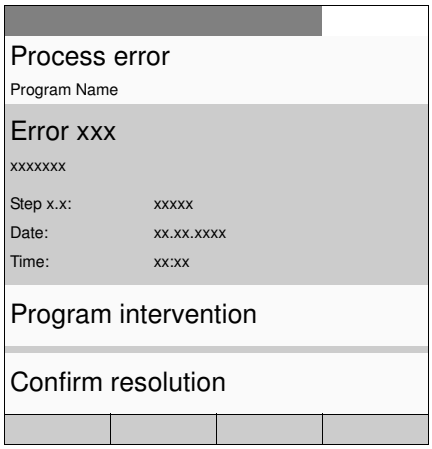
**Display while program is in progress:**




**Procedure in case of error:**

▶ If an error occurs during operation, resolve the error and confirm error resolution

▶ Select *"Confirm error resolution"* -Function



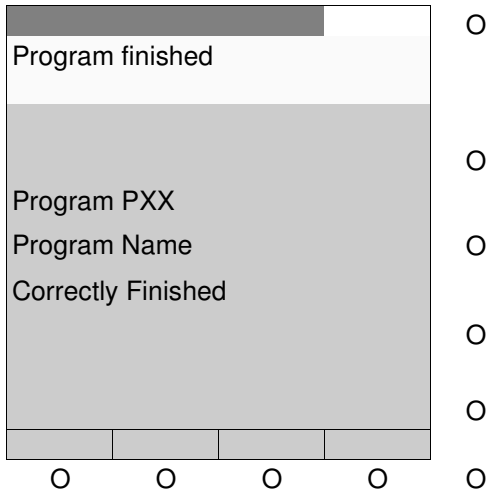

▶ If the error persists -->see Chap. 16 "Errors"!

▶ If the error cannot be rectified, technical support must be informed

**Danger**
If smoke is emitted or water escapes, immediately **press Emergency Stop** and disconnect the device from the building power supply. Call technical support to have system repaired.

▶ End of program is displayed and additionally indicated by flashing process status display

**Display for end of program on LS:**





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# 12 Unloading

**Display for end of program on US:**

| |
|---|
| Correctly Finished |

- ▶ Attach the transfer cart to the device
- ▶ Open washing chamber door on US with activity button ⏚
- ▶ Withdraw washed items (Fig. 581)

**Caution**
The washed items and washing chamber are hot! Always wear protective goggles and gloves when unloading.

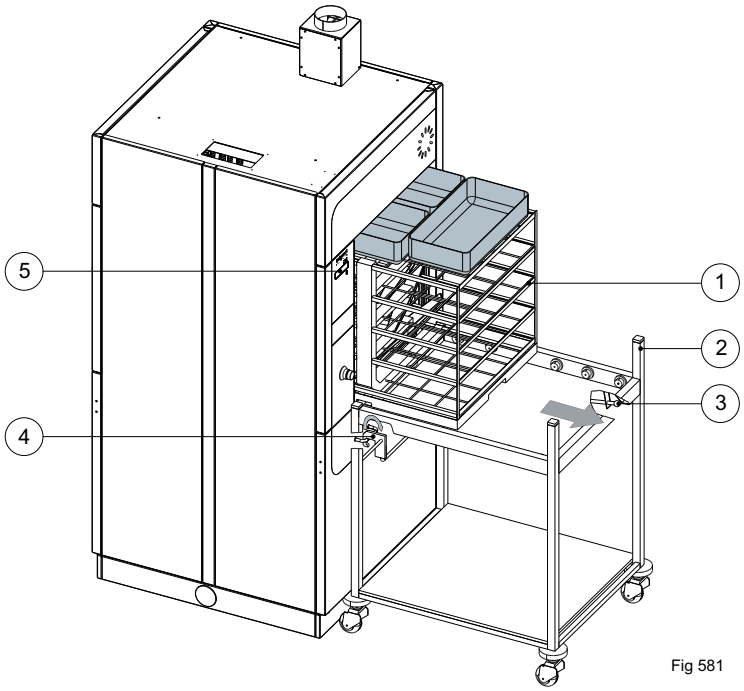


Fig 581

1 Rack
2 Transfer cart
3 Interlock
4 Attachment and detachment hook
5 Operating unit

- ▶ Close washing chamber door on US with activity button ⏚
- ▶ Device is ready for reloading from loading side
- ▶ Visually inspect cleaning result. *If washed items are still contaminated, repeat washing with the same program!*

**Caution**
There must be no more contaminations *(incrustations, deposits)* visible.

- ▶ Detach the transfer cart using the interlock (Fig. 581 Pos. 3)
- ▶ Washed items are ready for further processing


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# 13 Switching off the device

- ▶ Switch the device off with button ⏻ after use
- ▶ Close utility shut-off valves

**Note**
All manually operated utility shut-off valves must be closed while the device is not operating.

**Note**
If the device is switched off at the main switch, the controller is no longer active. Consequently, the water level is not checked and, in the event of a broken valve, water can overflow.


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# 14 Daily maintenance and cleaning tasks

## 14.1 Maintenance in general

The operating company is responsible for carrying out maintenance and cleaning work.

**Danger**
Before performing any maintenance work on components exposed to live electricity, the main switch must be switched off and secured against being switched back on.

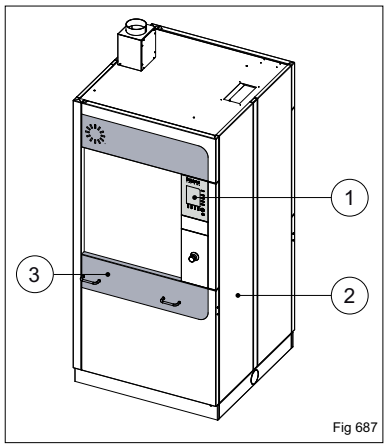
Only carry out maintenance and cleaning work wearing safety goggles and gloves! Contamination residues can cause infections!

## 14.2 Maintaining the device

The device must be cleaned and maintained for reasons of hygiene.

**Caution**
Never spray the device for cleaning. The device is not waterproof.

▶ Clean outside surface of the device




1 Operating panel
2 Chrome steel surface
3 HI-MACS Synthetic surface

*For outside cleaning, clean each surface of the device with a suitable cleaning and maintenance agent.*

Recommended cleaning agents:

| | |
|---|---|
| HI-MACS Synthetic surface | Moist cloth and mild cleaning agent |
| Operating panel | Commercially available glass cleaning agent |
| Chrome steel surface | Maintenance oil |

**Caution**
**Do not use any solvents** for cleaning!

## 14.3 Maintenance of the lower wash arm

**Warning**
Pointed or sharp objects can cause injuries when cleaning the device.

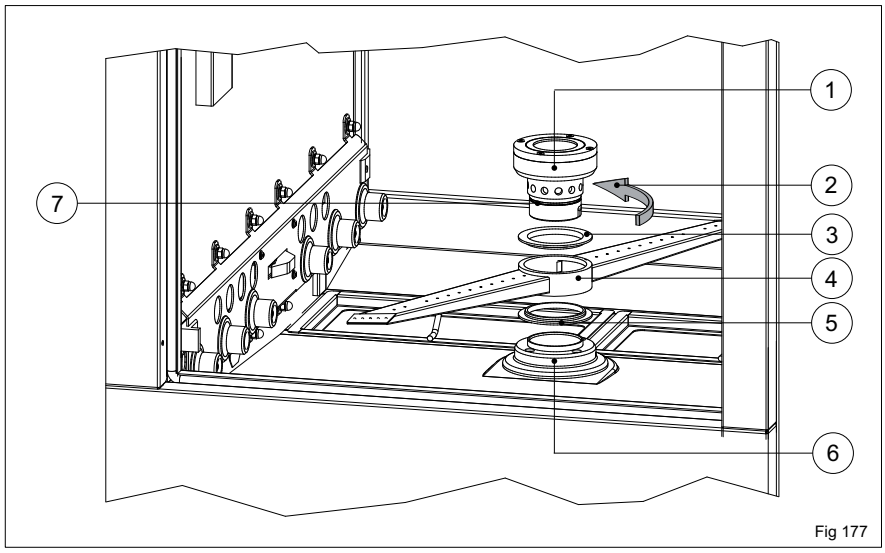


Fig 177

1 Clamp bearing
2 Direction of rotation for loosening
3 Upper bearing bush
4 Lower wash arm
5 Lower bearing bush
6 Supporting bearing
7 Sealing O-ring for clamp bearing

- ▶ Twist the clamp bearing (Fig. 177 Pos.1) counter-clockwise and pull it upwards
- ▶ Disassemble the remaining components acc. to Fig. 177
- ▶ Check the seal on the clamp bearing (Fig. 177 Pos.7) for damage
- ▶ Check wash arm (Fig. 177 Pos.4) for clogged nozzles and clean as required
- ▶ Clean the bearing bushes (Fig. 177 Pos.3+5), check for wear and replace as required

  Replacement criteria: Score marks or deep scratches
- ▶ Reassemble components

**Note**
The rinsing nozzles of the lower wash arm must point upwards!

- ▶ Check rotation of the wash arm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## 14.4 Maintenance of the upper wash arm

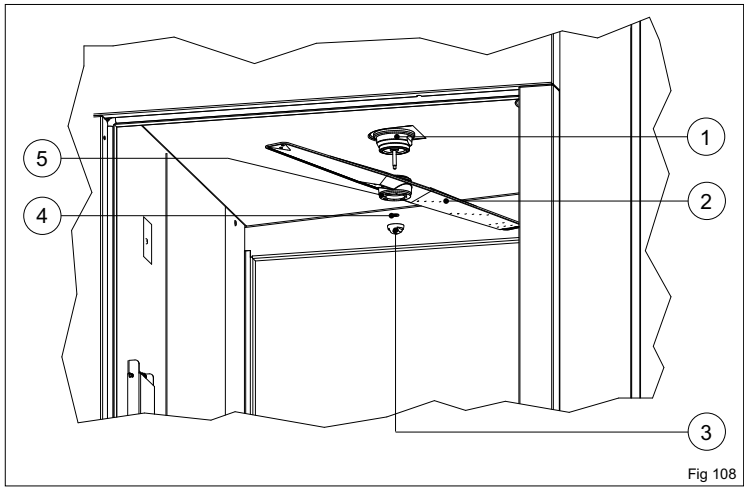

Fig 108

1 Wash arm sleeve
2 Upper wash arm
3 Cap nut
4 Slide ring
5 Rotor bearing

▶ Undo cap nut (Fig. 108 Pos.3)

**Note**
Do not lose the slide ring (Fig. 108 Pos.4)!

▶ Disassemble the remaining components acc. to Fig. 108
▶ Check wash arm (Fig. 108 Pos.2) for clogged nozzles and clean as required
▶ Check rotor bearing (Fig. 108 Pos.5) for wear and replace as required
Replacement criteria: Score marks or deep scratches
▶ Reassemble components

**Note**
The rinsing nozzles of the upper wash arm must point downwards!

▶ Check rotation of the wash arm

## 14.5 Cleaning fine screens and coarse screen

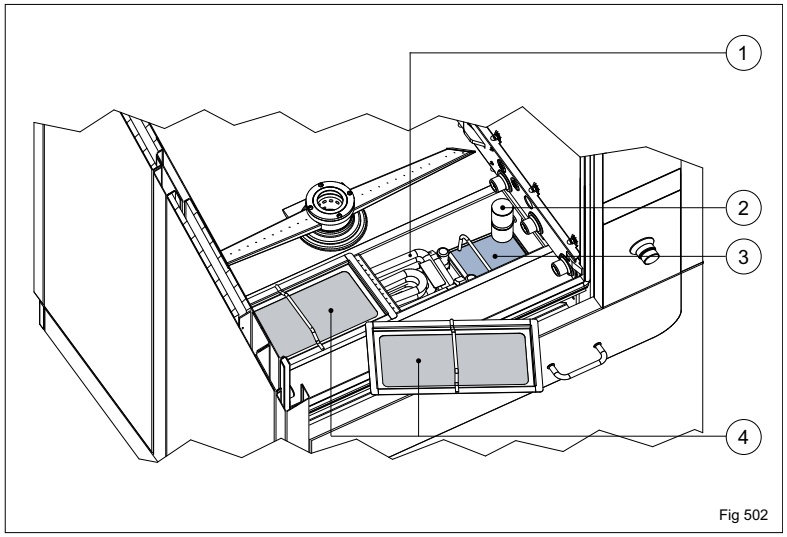

Fig 502

1 Tank heating elements
2 Level floats
3 Coarse screen
4 Fine screen

- ▶ Remove fine screens (Fig. 502 Pos.4) and clean as required
- ▶ Remove coarse screen (Fig. 502 Pos.3) and clean as required

**Caution**
The tank heating elements can be very hot!

- ▶ Remove foreign objects from washing chamber
- ▶ Reinsert coarse screen correctly
- ▶ Reinsert fine screens correctly

**Caution**
Never operate the device without fine screens and coarse screen!


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# 15 Device does not clean properly

## 15.1 Checking the device

- Has the right program been selected for the items to be washed?
- Do the wash arms rotate? (see Chap. 14 "Daily maintenance and cleaning tasks")
- Are the wash arms correctly installed? (see Chap. 14 "Daily maintenance and cleaning tasks")
- Are the wash arm nozzles clogged? (see Chap. 14 "Daily maintenance and cleaning tasks")
- Are the screens contaminated or not inserted? (see Chap. 14.5 "Cleaning fine screens and coarse screen")
- Does the rack docking system of the device function properly?
- Are the exhaust air, waste water and utility connections correctly established? (see Chap. 5 "Preparation of the device") ***The checks must be performed by technical support!***

## 15.2 Checking the dosing system

**Warning**
Wearing protective goggles and gloves is compulsory when handling any dosage media!

Follow safety instructions of the dosage media manufacturer!

- Are there sufficient amounts of dosage media in the containers? (see Chap. 16.1 "Error display without process termination")

## 15.3 Checking rack loading

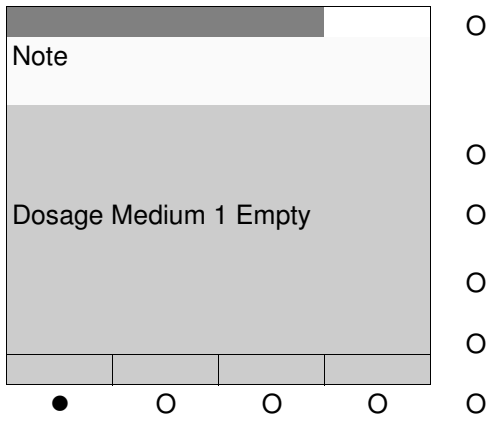
- Are the items to be washed properly loaded on the appropriate rack as specified? (see Chap. 8 "Loading and identifying racks")
- Are the washing nozzles on the rack clogged? (see Chap. 8.1 "Loading racks")
- Is the rack correctly inserted? (see Chap. 10.1 "Manual loading")
- Have the items to be washed been pre-treated as specified? (see Chap. 4 "Pre-treatment of the medical devices")

# 16 Errors

## 16.1 Error display without process termination

If an error occurs while the program is in process, a message is displayed on the operating unit.

Example of a message display:




| Operating unit display | Cause | Remedy |
|---|---|---|
| Dosage medium XXX empty | Container for dosage medium is empty.<br>Empty indicator float incorrectly fitted or defective. | 1) Supply new container.<br>2) Withdraw the empty-indicator lance from the empty container and correctly insert it into the new container.<br>3) Activate washing program.<br>***Warning!***<br>***Always wear protective goggles and gloves when refilling the dosage media!***<br>***Follow safety instructions of the dosage media manufacturer!*** |
| Error 118<br>Program recognition | Rack position in washing chamber is not correct.<br>Reed sensor for *"Automatic program recognition"* defective. | Withdraw and reinsert rack.<br>Inform technical support. |
| Door locked<br>Select Pr once more | If the program is terminated with button ⏻ , the washing chamber door remains locked. | New program can be selected. |
| Sensor difference<br>is too large | Difference between monitoring sensor and control sensor is too large (+- 2℃). | New program can be selected.<br>Inform technical support immediately. Recalibrate the sensors at a minimum of 80℃. |
| Replace filter | The sterile filter for the drying system is clogged. | Inform technical support immediately. |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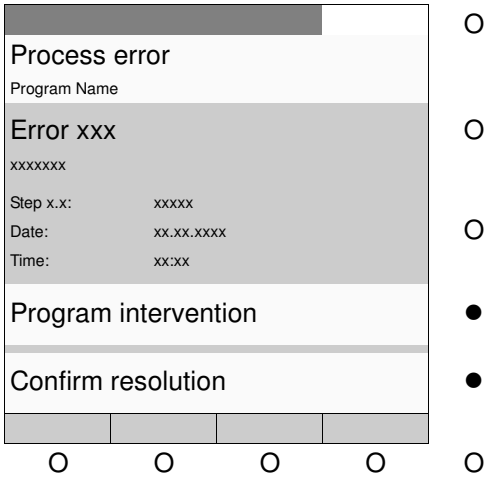
| Operating unit display | Cause | Remedy |
|---|---|---|
| Periodic servicing | Maintenance prompt after specified number of batches. (Generally every 1500 batches) | New program can be selected.<br>Initiate service call by contractual partner. |
| Exhaust facility defective | Building exhaust facility failure. | New program can be selected.<br>Inform technical support immediately. |
| Peak load shutdown | The building peak load management has blocked the device as a load. | A new program cannot be selected.<br>Wait until it is enabled once again. |
| No Communication with Batch Doc Syst | Connection to PC for batch recording is interrupted. | New program can be selected.<br>Re-establish connection between device and PC for batch recording. |

## 16.2 Error display with process termination

**Warning**
Report error displays with process termination to technical support immediately! Do not continue working with the device under any circumstances!

If an error occurs while a program is in progress, the process is interrupted automatically and the error is indicated on the display.

Example of error display:




## 16.3 Device will not operate

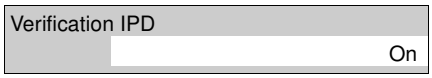
- Is the main switch turned on? ***To be checked by technical support only!***
- Error is shown on the display? (see Chap. 16 "Errors")
- Is the building power supply interrupted?
- Are the washing chamber doors correctly locked? (see Chap. 5 "Preparation of the device")
- Are the fuses intact? ***To be checked by technical support only!***

# 17 Options

## 17.1 Independent Process Data management IPD

With automatic verification, the ongoing process is interrupted with the relevant error message. The function can be switched on and off from the operating unit. If the function is switched *"On"* the process is terminated, if switched *"Off"*, only a message is shown on the display.

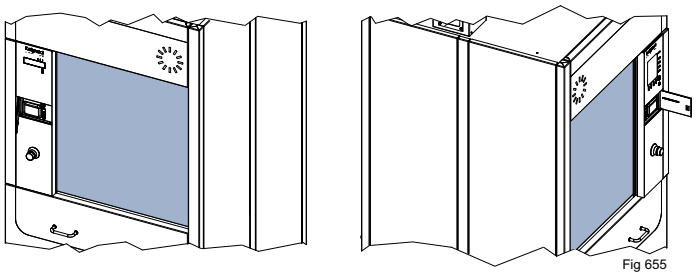
Activation:

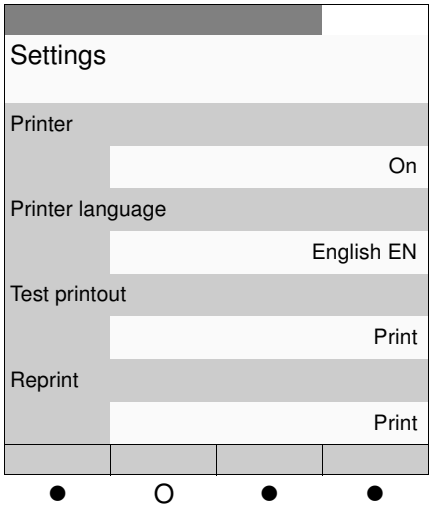



## 17.2 Built-in printer US / LS

### 17.2.1 Function

The built-in printer is used for printing out operating data such as program steps, errors and program interruptions.




● O ● ● O

O ***Printer:***

Printer *On/Off/Only in case of error*

***Printer language:***

● Selection of printer language from three languages

***Test printout:***

● Direct activation of a test printout

***Reprint:***

● Activation of printout for last batch.

●

### 17.2.2 Replacing the paper roll

- ▶ Open flap by pressing left/centre (printer on LS) or right/centre (printer on US)
- ▶ Replace roll
- ▶ Close flap. Guide paper through paper slit
- ▶ Printer ready for operation again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# 18 Conformity and certifications

## *KONFORMITÄTSERKLÄRUNG*
## *DÉCLARATION DE CONFORMITÉ*
## *DECLARATION OF CONFORMITY*

**Belimed AG**
**Dorfstrasse 4**
**CH-6275 Ballwil**

Wir erklären in alleiniger Verantwortung, dass der Reinigungs- und Desinfektionsautomat
Nous déclarons sous notre propre responsabilité que l'automate de lavage et de désinfection
Under our sole responsibility we herewith declare that the washer and disinfectors

Typ: **WD 290** (09) Serien-Nr.: **994000094001** **994000094007**

nach Anhang IX der Richtlinie 93/42/EWG, als ein Medizinprodukt der Klasse IIA eingestuft wird und gemäss der Bestimmungen der Richtlinien
est conforme, selon l'annexe IX de la directive 93/42/CEE sur les dispositifs médicaux de la classe IIA, aux directives des normes
according to annex IX of directive 93/42EEC, is rated as a médical device of class IIA and under the terms of reference

**93/42/EWG**
**93/42/CEE**
**93/42/EEC**

mit den folgenden harmonisierten Normen, nationalen Normen oder normativen Dokumenten übereinstimmt.
selon les normes harmonisées, les normes nationales ou autres documents normatifs suivants.
is confirm with the following harmonised standards, national standards or other normative documents.

| | | |
|---|---|---|
| **Sicherheit** | **EN 61010-1:** 2001 | **IEC 61010-1:** (ed.2) |
| | **EN 61010-2-040:** 2005 | **IEC 61010-2-040:** (ed.1) |
| **EMV** | **EN 61326-1:** 2006 | **IEC 61326-1:** 2005 |
| | **EN 61326-3-11:** 2000 | **IEC 61326-3-11:** 2000 |
| | **EN 61326-3-12:** 2005 | **IEC 61326-3-12:** 2004 |
| **SVGW** | **W/TPW106:** 2001 | **EN 61770** |
| **Typenprüfung** | **EN ISO 15883-1:** 2006 | |

| | |
|---|---|
| Konformitätsbewertungsverfahren<br>Procédure d'évaluation de la conformité<br>Conformity assessment procedure | Nach 93/42 EWG, Anhang II<br>(Vollständiges Qualitätssicherungssystem) |
| Konformitätsbewertungsstelle<br>Organisme notifié<br>Notified Body | TÜV NORD CERT GmbH<br>Langenmarkstrasse 20, 45141 Essen, Gemany<br>0044 |

Ballwil, 27. April 2009

W. Schürpf
Head Research & Development

E. Ammann
Head Application / Process Engineering

# 19 Glossary

**Authorised persons** — Approved persons, more particularly, persons who have been granted certain rights.

**Cleaning** — Removal of contaminations from surfaces to be cleaned by means of an aqueous medium, with or without process chemicals as required.

**Controller** — Device that guides the washer/disinfector step by step through the required phases of the process cycle (or cycles), or the process, in accordance with the specified, process-relevant parameters.

**Disinfection** — Reduction of the number of viable micro-organisms on a product to a predefined level suitable for its continued handling or use.

**Error** — Condition of a functional unit in which it is incapable of fulfilling a required function, not including incapacity due to maintenance work or other planned actions or due to absence of required external agents.

**Error display** — Detection by the automatic controller that the specified process variables for the process cycle of the washer/disinfector were infringed.

**Gloves** — Acid and alkali resistant gloves

**Hazard** — Potential source of damage.

**Installation qualification** — Illustrative and documenting evidence that the device has been equipped and installed in accordance with the relevant specifications.

**Intended use** — Use of a device in accordance with the specifications laid down in the user instructions.

**Load** — Collective term used to describe all utensils, appliances and materials that are simultaneously inserted into a washer/disinfector for the purpose of treating them in a process cycle.

**LS** — Loading side

**Medical devices** — All instruments, apparatuses, devices, software, materials or other objects, used by themselves or in connection with each other, including the software specially designed by the manufacturer for diagnostic and/or therapeutic purposes and used for the proper function of the medical device, that are intended by the manufacturer to be used in humans for the following purposes:

- Diagnosis, prevention, monitoring, treatment or alleviation of diseases;
- Diagnosis, monitoring, treatment, alleviation or compensation of injuries or disabilities;
- Examination, replacement or modification of the anatomic structure or of a physiological process

and whose proper main function in or on the human body is neither achieved by pharmacological, immunological nor metabolic means, but whose mode of action may be supported by such means.

**Operators** — Persons who load and unload the device and perform basic cleaning and maintenance work.

**Operating unit** — Interface between operator and system. The operating unit may be equipped with buttons, switches or a touch panel.

**Operating company** — Persons or companies who are responsible for use and maintenance of devices. The operating company is the legal proprietor of the devices.

**Performance qualification** — System by which the process cycle can be interrupted or modified depending on requirements; illustrative and documenting evidence that the device, as it is installed and operated according to the operating procedures, works consistently in accordance with the predefined criteria and therefore products are obtained


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| | |
|---|---|
| | that fulfil their specifications, i.e. the washing/disinfection device delivers products that are cleaned and disinfected according to the required standard. |
| **Protective goggles** | Acid and alkali resistant fully sealed protective goggles |
| **Rack** | Device used for correct loading and cleaning of washing utensils. |
| **RKI** | The mission assigned to the **R**obert **K**och **I**nstitute includes both observation of the occurrence of diseases and relevant health hazards in the population, as well as the task of deriving and scientifically establishing the required measures for effective protection of the health of the population. |
| **SOP** | A **S**tandard **O**perating **P**rocedure is a document which describes the procedure to be followed within a work process which forms part of the operations designed to achieve the business objectives of an enterprise. Frequently recurring work procedures are described in texts and provided for guidance to the persons implementing the tasks. |
| **Tank** | Container permanently installed in the washer/disinfector for storage of solutions required during the process. |
| **Technical service** | Ensures proper function of all systems, machines and devices and is responsible for servicing and maintenance work. |
| **US** | Unloading side |
| **Validation, process validation** | Documented procedure for obtaining, recording and interpreting the test results required in order to demonstrate that a procedure consistently complies with the prescribed specifications. |
| **Washer/Disinfector (WD)** | Device used for cleaning and disinfecting medical devices and other objects used in medicine, dentistry, pharmacy and veterinary medicine.<br>*Note: Device types designed specifically for cleaning clothing or other laundry items are not included. Specifications for devices intended for use in sterilization or designated "sterilizers" are laid down in other standards, e.g. EN 285.* |
| **Washing chamber** | The part of the washing/disinfection device in which the load is treated.<br>*Note: Steam generators, piping, e.g. drains and connections, from which the chamber can be disconnected, are not defined as part of it.* |
| **Washing chamber door** | Device for closing and sealing the chamber. |

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# 21 Notes


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